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**Patent and Trademark Office**

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/968,208    11/12/97    HIGUCHI

R    9397

022896    IM22/0911  
PATTI SELAN, PATENT ADMINISTRATOR  
APPLIED BIOSYSTEMS  
850 LINCOLN CENTRE DRIVE  
FOSTER CITY CA 94404

EXAMINER

SNAY, J

ART UNIT

PAPER NUMBER

1743

DATE MAILED:

09/11/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

08/968,208

Applicant(s)

HIGUCHI, RUSSELL

Examiner

Jeffrey R. Snay

Art Unit

1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 30-47 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 30-47 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 35.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 06/27/01 has been entered.
2. The amendment filed 02/14/00 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. The reasons for this objection are set forth in the previous Office action, paper no. 23. Applicant is required to cancel the new matter in the reply to this Office Action.
3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.
4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
  1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 30-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hafr (1989) in view of Mackay (EP 0266881) and Schnipelsky et al (US 5,229,297).

Each of Haff and Mackay are relied upon for the reasons set forth in paragraph 4 of the last Office action. Schnipelsky et al disclose a method and apparatus for monitoring PCR reactions in which a closed cuvette is provided such that detection reagents can be provided without exposing the reaction contents to the atmosphere, and for enabling on-line analysis. It would have been obvious to one of ordinary skill in the art to further provide the closed cuvette device of Schnipelsky et al in order to enable online analysis of the PCR reactions.

6. Claims 30-47 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over 1-6, 8-10 and 12-27 of copending Application No. 08/266061. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

See paragraph 3 of the previous Office action, paper no. 18. Regarding the newly recited limitation of a sealed reaction vessel, such would have been obvious for the same reasons applied in the grounds of rejection, above.

7. The declaration filed under 37 CFR 1.132 filed 07/27/01 is insufficient to overcome the rejection of claims 30-47 as set forth above. The declaration states that at the time of invention, there was a general belief by practitioners that dyes such as ethidium bromide would interfere with assay performance, e.g. by inhibiting the polymerase used to perform primer extension. However, the newly cited reference to Schnipelsky et al establishes that it was known to provide a cuvette for containing detection reagents associated with a PCR reaction mixture in a closed vessel such that the reagents can be provided for analysis without interfering with the reaction and without the necessity of removing reaction products from the cuvette.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey R. Snay whose telephone number is (703) 308-4032. The examiner can normally be reached on Mon-Fri.

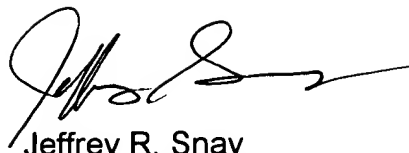
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (703) 308-4037. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-7718 for regular communications and (703) 308-3599 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 306-5665.

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A handwritten signature in black ink, appearing to read 'Jeffrey R. Snay', with a long horizontal flourish extending to the right.

Jeffrey R. Snay  
Primary Examiner  
Art Unit 1743

jrs  
September 10, 2001